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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,426	12/12/2005	Limin Li	5398-011-27 NATL	6259

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	PAPER NUMBER
1632	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,426	LI ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-137* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-137* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-18, 33, 34, 136 and 137, drawn to a purified mammalian RapR7 protein, a protein which comprises the amino acid sequence substantially as set forth in SEQ ID No. 4 or 7, a purified protein encoded by a nucleic acid capable of hybridizing to a DNA comprising a sequence consisting of the coding region of SEQ ID No. 2 or 5, a purified derivative or analog of the mammalian RapR7 protein display one or more functional activities of said RapR7 protein or capable of binding to an antibody against a mammalian RapR7 protein, a purified fragment of a mammalian RapR7 protein, and a pharmaceutical composition comprising said protein.

Group II, claim(s) 19-21, 35 and 104-113, drawn to an antibody which is capable of binding to a mammalian RapR7 protein, a pharmaceutical composition comprising said antibody, and a method of producing said antibody.

Group III, claim(s) 22-32, drawn to an isolated nucleic acid encoding a mammalian RapR7 protein as set forth in group I, a recombinant cell containing said nucleic acid, and a method of producing a mammalian RapR7 protein by using the recombinant cell.

Group IV, claim(s) 36-59 and 120-130, drawn to a method for generating a genetically modified cell having altered sensitivity to rapamycin comprising introducing into the genome of a cell of an organism a knockout DNA construct, and a cell comprising said knockout DNA construct.

Group V, claim(s) 60, 61 and 63-65, drawn to a method for treating a mammal having a cancer comprising administering to said mammal an agent that **reduces** the expression of the RapR7 gene in cells of said cancer.

Group VI, claim(s) 60, 62-64 and 66, drawn to a method for treating a mammal having a cancer comprising administering to said mammal an agent that **causes** the expression of the RapR7 gene in cells of said cancer.

Group VII, claim(s) 60, 63, 64 and 67, drawn to a method for treating a mammal having a cancer comprising administering to said mammal **an agent comprising a RapR7 protein** or a therapeutically equivalent fragment thereof.

Group VIII, claim(s) 68-74, drawn to a method for diagnosing a cancer or a predisposition to a cancer in a mammal comprising determining **an expression level of the RapR7 gene** in cells of

said mammal by using one or more polynucleotide probes comprising a nucleotide sequence of RapR7 gene.

Group IX, claim(s) 75, 77-80, drawn to a method for diagnosing a cancer or a predisposition to a cancer in a mammal comprising determining **the level of abundance of RapR7 protein** in cells of said mammal by using antibody.

Group X, claim(s) 76-80, drawn to a method for diagnosing a cancer or a predisposition to a cancer in a mammal comprising determining **the level of activity of said RapR7 protein** in cells of said mammal.

Group XI, claim(s) 81-87, drawn to a method for evaluating rapamycin resistance in a cell comprising determining **an expression level of a RapR7 gene** in said cell by using one or more polynucleotide probe comprising a nucleotide sequence of RapR7 gene.

Group XII, claim(s) 88 and 90-93, drawn to a method for evaluating rapamycin resistance in a cell comprising determining **a level of abundance of a protein** encoded by RapR7 gene in said cell by using antibody.

Group XIII, claim(s) 89-93, drawn to a method for evaluating rapamycin resistance in a cell comprising determining **the level of activity of a protein** encoded by RapR7 gene in said cell.

Group XIV, claim(s) 94, 95 and 97, drawn to a method for **regulating rapamycin resistance** in a cell comprising contacting said cell with an agent that **reduces** the expression of said RapR7 gene in said cell.

Group XV, claim(s) 94, 95 and 98, drawn to a method for **regulating rapamycin resistance** in a cell comprising contacting said cell with an agent that **causes** the expression of said RapR7 gene in said cell.

Group XVI, claim(s) 96 and 97, drawn to a method of **regulating growth** of a cell comprising contacting said cell with an agent that **reduces** the expression of said RapR7 gene in said cell.

Group XVII, claim(s) 96 and 98, drawn to a method of **regulating growth** of a cell comprising contacting said cell with an agent that **causes** the expression of said RapR7 gene in said cell.

Group XVIII, claim(s) 94, 95 and 99, drawn to a method for **regulating rapamycin resistance** in a cell comprising contacting said cell with an agent that **comprises a RapR7 protein** or a therapeutically equivalent fragment thereof.

Group XIX, claim(s) 96 and 99, drawn to a method for **regulating growth** in a cell comprising contacting said cell with an agent that **comprises a RapR7 protein** or a therapeutically equivalent fragment thereof.

Group XX, claim(s) 100-102 and 114-116, drawn to a method of identifying an agent that is capable of regulating rapamycin resistance comprising comparing inhibitory effect of rapamycin on cells expressing said RapR7 gene with and without said agent, wherein said agent reduces expression of the RapR7 gene, and an agent that **reduces expression of the RapR7 gene**.

Group XXI, claim(s) 100, 101, 103, 114, 115 and 117-119, drawn to a method of identifying an agent that is capable of regulating rapamycin resistance comprising comparing inhibitory effect of rapamycin on cells expressing said RapR7 gene with and without said agent, wherein said agent causes expression of a normal version of the RapR7 gene, and an agent that **causes expression of a normal version of the RapR7 gene.**

Group XXII, claim(s) 131-133, drawn to a **microarray** for diagnosing rapamycin resistance, said microarray comprises one or more polynucleotide probe having a nucleotide sequence in a RapR7 gene.

Group XXIII, claim(s) 134, drawn to a **kit for diagnosis** of rapamycin resistance comprising in one or more containers one or more polynucleotide probes, wherein each said polynucleotide probe comprises a nucleotide sequence in a RapR7 gene.

Group XXIV, claim(s) 135, drawn to a **kit for screening** for agents which regulates rapamycin resistance and/or tumorgenesis comprising in one or more containers (i) the cell of claim 120, (ii) tetracycline or a derivative or analog thereof, and (iii) rapamycin or a derivative or analog thereof.

2. The inventions listed as Groups I-XXIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the putative common special feature shared by groups I-III, VII-IX, XI, XII, XVIII, XIX and XXII-XXIV is either the RapR7 amino acid sequence or the nucleic acid encoding said RapR7 amino acid sequence. Hillman et al., 2001 (WO 01/72777 A2) discloses a nucleotide sequence (N-Geneseq Accession No. ABA83007) encoding a human transcription factor TRFX-34, which is 87.2% identical to the nucleotide sequence of SEQ ID No. 2 from nucleotide 363 to nucleotide 2856, and the nucleotide sequence would be able to hybridize to the sequence of SEQ ID No. 2. Hillman also discloses the protein sequence of human transcription factor TRFX-34 (A-Geneseq Accession No. ABB50183), which is 90.8% identical to the amino acid sequence of SEQ ID No. 3 from amino acid residue 123 to amino acid residue 951. It is noted that amino acid residues 123-951 of SEQ ID No. 3 is the amino acid sequence of SEQ ID No. 4. Therefore, the amino acid sequence of Accession No. ABB50183 is 90.8% identical to the amino acid sequence of SEQ ID No. 4. The amino acid sequence disclosed by Hillman is substantially identical to SEQ ID No. 4, it is a protein encoded by a nucleic acid capable of hybridizing to the DNA sequence of SEQ ID No. 2, it can bind to an antibody directed against a mammalian RapR7 protein, and it contains a fragment of a mammalian RapR7 protein. The protein sequence disclosed by Hillman can be used to produce an antibody directed against a mammalian RapR7 protein. Thus, there is no special technical feature contributed by the instant invention over the prior art.

3. Groups V-VII do not share common special technical feature because they use different agent for different biological functions: an agent reducing expression of RapR7, an agent causing expression of RapR7, and an agent comprising a RapR7 protein. Similarly, groups XIV-XXI do not share special technical feature. Groups VIII-X do not share special technical feature because they use different agent for different purposes: determining expression level of the RapR7 gene, determining level of abundance of RapR7 protein, and determining level of activity of the RapR7 protein. Similarly, groups XI-XIII do not share special technical feature. Group IV, groups V-VII, groups VIII-X, groups XI-XIII, groups XIV, XV, XVIII, groups XVI, XVII, XIX, and groups XX-XXI also do not share special technical feature because they are drawn to different methods having different objectives, method steps, reagents and schedules used, and criteria of success. Further, groups I-III, VII-IX, XI, XII, XVIII, XIX, XXII-XXIV and groups IV-VI, X, XIII-XVII, XX, XXI do not share special technical feature. In view of the reasons set forth above, Groups I-XXIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2.

4. Upon election of any of groups I-III, VII-IX, XI, XII, XVIII, XIX, XXII-XXIV, further restriction is required. Applicants is required to elect SEQ ID Nos. 2-4 or SEQ ID Nos. 5-7 for examination because SEQ ID Nos. 2-4 represent mouse RapR7 sequences and SEQ ID Nos. 5-7 represent human RapR7 sequences. They have different core nucleotide sequences and different protein properties. It is noted that this is a restriction rather than an election of species. Since there are 13 groups in this section and each group has two choices, therefore, there are 26 groups in this section. Excluding groups I-III, VII-IX, XI, XII, XVIII, XIX, XXII-XXIV, there are 11 groups left. Thus, there are a total of 37 groups, i.e. 26 groups + 11 groups.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected

process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

/Shin-Lin Chen/
Primary Examiner, Art Unit 1632